The value of shock index, modified shock index and age shock index to predict critical outcomes in a district level emergency centre

by

Patrick Aleka-umbe Aleka

Bachelor of Medicine, Bachelor of surgery (University of Calabar, Nigeria)

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Supervisors

Dr Clint Hendrikse

Dr Candice Van Koningsbruggen

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Declaration

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Abbreviations

AMI	Acute Myocardial Infarction
ASI	Age shock index
AUROC	Area under receiver operating characteristic
EC	Emergency Centre
ED	Emergency Department
HECTIS	Hospital and Emergency Centre Tracking Information System
HCU	High Care Unit
HR	Heart rate
HREC	Human Research Ethics Committee
ICU	Intensive Care Unit
LMIC	Low- and middle-income countries
MAP	Mean Arterial Pressure
MIC	Middle-income countries
MSI	Modified shock index
RHT	Refusal of hospital treatment
SATG	South African triage Group
SATS	South African triage scale
SBP	Systolic Blood Pressure
SI	Shock Index
STEMI	ST elevation Myocardial Infarction
UCT	University of Cape Town

PART A: MANUSCRIPT IN ARTICLE FORMAT

(AFJEM)

Title page

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Patrick Aleka, Candice Van Koningsbruggen, Clint Hendrikse

Author list

1. Patrick Aleka, MBBCh
   Division of Emergency Medicine, Department of Surgery, F51-62, Old Main Building, Groote Schuur Hospital, Faculty of Health Sciences, University of Cape Town, Observatory, 7925

2. Candice Van Koningsbruggen, MBChB MMed FCEM
   Division of Emergency Medicine, Department of Family Medicine, University of Stellenbosch, 7530

3. Clint Hendrikse, MBChB MMed FCEM
   Division of Emergency Medicine, Department of Surgery, F51-62, Old Main Building, Groote Schuur Hospital, Faculty of Health Sciences, University of Cape Town, Observatory, 7925

Corresponding author: Patrick Aleka
Division of Emergency Medicine, Department of Surgery, F51-62, Old Main Building, Groote Schuur Hospital, Faculty of Health Sciences, University of Cape Town, Observatory, 7925.
+27 21 650 1829

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Abstract

Introduction

Triage is the first and single most important step in patients' journey through an Emergency Centre (EC) and directly impacts the time to critical actions. Vital signs influence triage decisions, predict hospital admission and in-hospital mortality. The shock index (SI), modified shock index (MSI) and age shock index (ASI) are clinical markers derived from vital signs and correlate with tissue perfusion in critically ill patients. This study aimed to assess the value of SI, MSI and ASI to predict critical outcomes in all adult patients presenting to a district level emergency centre in South Africa.

Methods

This diagnostic study was performed as a retrospective observational study, using data from an existing electronic database at a district level hospital emergency centre over a period of 24 months. All adult patients who presented to Mitchells Plain Hospital were eligible for inclusion. Sensitivity, specificity and likelihood ratios were calculated for each variable as a predictor of critical outcomes with pre-determined thresholds.

Results

During the study period of 24 months, a total of 61 329 patients ≥ 18 years old presented to the EC with 60 599 included in the final sample. A red SATS triage category (+LR = 7.2) and SI ≥1.3 (+LR = 4.9) were the only two predictors of critical outcomes with any significant clinical value. The same two markers performed well for both patients with trauma and without trauma and specifically for patient who died while under the care of the emergency centre.

Discussion

The study demonstrated that patients with a SI≥1.3 have a significantly higher likelihood of having a critical outcome, whether the presenting complaint is trauma related or not, especially to predict mortality while under the care of the EC. Incorporating this marker as triage alerts could expedite the identification of patients with critical outcomes and improve patient throughput in the emergency centre.

Background

Triage is the first and single most important step in patients' journey through an Emergency Centre (EC). (1,2) The information derived from the triage process directly impacts the time to critical actions and promotes distributive justice so that that the greater good happens to the greater number of people. (3)Evidence based triage systems that is locally validated improves patient outcomes and ultimately saves lives.(4,5) While the most validated triage systems for ECs globally include the Canadian Triage Assessment Scale, Australian Triage Score, Manchester Triage System, and Emergency Severity Index (ESI), (6)the South African Triage Scale (SATS) has gained more acceptance in various low- and middle-income countries (LMICs). (4,5,7) Despite their differences, the all-encompassing goal is to identify patients in need of emergency treatment and to prioritize the sickest patients first. (6)

Vital signs influence triage decisions , (8) predict hospital admission and in-hospital mortality. (9,10) Studies have attempted to use clinical discriminators exclusively in a bid to simplify and quicken the triage process, with varying results. (11–13) This is especially relevant in LMICs where a lack of appropriately trained staff is a significant barrier.(14) The combination of vital signs and discriminators produce a more robust and effective triage tool. (12) The shock index (SI), modified shock index (MSI) and age shock index (ASI) are clinical markers which correlate with tissue perfusion in critically ill patients.(15,16) SI (the ratio of heart rate to systolic blood pressure) has been shown to be a better predictor of patient outcomes than conventional vital signs. (17) Despite its increasing popularity, very few studies have assessed its value in predicting critical outcomes in the general cohort of patients presenting to ECs. The ASI incorporates the age of a patient, taking into consideration the differences in physiology at both extremes of age, (18) and the MSI uses mean blood pressure instead of systolic blood pressure, because mean blood pressure changes earlier in the critically ill and is a reasonable predictor of disease severity. (16) Zarzaur et al (19) found that older patients with an ASI ≥50 suffered nearly 10% mortality while those with ASI ≥60 suffered 15% mortality. An MSI value of >1.3 is associated with an increased probability of ICU admission and death as shown in the initial study by Liu et al. (16) Studies by Shangguan et al also demonstrated an MSI threshold ≥0.9 to be a predictor of mortality and MACE within seven days in STEMI patients with a myocardial infarct. (20)

The value of these clinical markers to predict critical outcomes has been assessed in high-income countries (HICs) but the external validity is questioned. LMICs are faced with a higher disease burden with 98% of all deaths in children younger than 15 years occurring here. A total of 83% and 59% of deaths at 15–59 and 70 years respectively, occur in LMICs. (21) The SATS is validated in South Africa

with its quadruple burden of disease (maternal, new born and child health; HIV/AIDS and Tuberculosis; non-communicable diseases; violence and injury). (22) These clinical markers can potentially complement the triage tool, resulting in prompt allocation of resources to patients at risk of critical outcomes. This study aimed to assess the value of SI, MSI and ASI to predict critical outcomes in all adult patients presenting to a district level emergency centre in South Africa.

Methods

Study design

This study is a retrospective observational study, analysing data from an existing database over a 24-month period.

Study setting

This study took place at Mitchells Plain Hospital, a large district hospital located in Cape Town, South Africa. It belongs to the Mitchells Plain Health District of the Western Cape Province Metro Region. It is located 32km from the central business district and caters to a diverse population of about 600,000 people. It serves the nearby communities of Mitchells Plain, a low- to middle-income population and Philippi a large informal settlement with mainly low-income families. The Emergency Centre (EC) attends to an average of 4000-4500 high acuity patients a month. (23) The burden of disease reflects the quadruple burden of South Africa: trauma and injuries, paediatrics, surgical and medical emergencies. Patients are triaged when they arrive in the EC with the South African Triage Scale (SATS) and their vital signs and details loaded into an electronic registry, Hospital and Emergency Centre Tracking and Information System (HECTIS). The overall admission rate is 37% (internal and transfers out), and there is no intensive care or high care facility at Mitchells Plain Hospital.

Study population and sampling

All adult patients (≥ 18 years of age) who presented to Mitchells Plain Hospital EC between 1st of January 2018 and the 31$^{st\ of}$ December 2019 (24-months) were eligible for inclusion. Inclusion criteria included all adult patients that presented to the emergency centre during the time period. A study period of 24 months was chosen to limit the effects of month-to month and seasonal variance. All cases with incomplete triage data were excluded, as well as duplicate cases.

Data collection and management

Eligible participants were identified from the electronic database, HECTIS, an official provincial application to manage patients' throughout in the EC. Demographical details, disposition data and

triage data for each participant meeting the inclusion criteria were extracted onto a spreadsheet and shock index (SI), modified shock index (MSI) and age shock index (ASI) were calculated (Table 1). Extracted data only included cases without missing triage information.

HECTIS is an electronic registry that captures information regarding patient demographics, location within the EC, ICD-10 diagnostic codes, and process times routinely. HECTIS also integrates the South African Triage Scale (SATS) and is used by nurses, clinicians and administrative personnel. Triage data is entered by nurses who are trained in using HECTIS and the application of the SATS tool. Triage accuracy is monitored as part of a continuous quality improvement project and frequent audits are performed. Clinical data is entered by clinicians and include ICD-10 coding and disposition data. Critical outcomes were defined as an EC disposition that included: (i) patients who died while under EC care, (ii) patients referred to a high care unit (HCU) or (iii) an intensive care unit (ICU), (iv) patients who required admission to the ward and (v) those who required transfer to tertiary/central hospitals. To ensure confidentiality, only de-identified data were exported.

Missing data or incomplete records

Patients with incomplete triage data will be excluded from the study as these need to be clearly documented vital signs for each participant. The number of missing cases will be clearly identified , together with the demographics of the patients, if the total missing data exceeds 5%. This will allow for comparison to be made between the relevant patients and the missing information. Data were cleaned and managed by the principal investigator, initially in a spreadsheet and then exported to the Statistical Package for the Social Sciences (SPSS) Version 28 for analysis. The data extraction process ensured that no cases with missing triage data were included from the beginning.

Data safety and monitoring

Data will be obtained from the HECTIS database as described above and further calculations and information will be performed on the data set. No identifying information will be collected and data will be exported anonymously. A request to the database manager will include only the variables listed above for the study period. Files will be stored centrally at the University of Cape Town (UCT) Division of Emergency Medicine offices and will be password protected. Study data and information will also be backed up on a cloud server weekly, with access only by study personnel.

Data Analysis

Data were presented using descriptive and inferential statistics. Data were analysed by the principal investigator with the help of SPSS Version 28. Continuous variables were all non-normally distributed and presented as medians and interquartile ranges, while categorical variables were presented as proportions and distributions. Non-random associations between groups (categorical variables) were assessed by using the Fisher's exact test or the X^2 test, depending on the sample characteristics. The Mann-Whitney U-test was used to test for statistically significant differences between groups with numerical data. Statistical significance was defined as p-value <0.5. Sensitivity, specificity and likelihood ratios were calculated for each variable as a predictor of critical outcomes with pre-determined thresholds. (Table 1): (16,19,24,25)

Table 1: Markers to be assessed

Marker	Definition	Thresholds assessed
Shock index (SI)	HR / SBP	≥0.7; ≥1.0 and ≥1.3
Modified shock index (MSI)	HR/MAP*	≥0.9 and ≥1.3
Age shock index (ASI)	SI x age (years)	≥50

SBP Systolic blood pressure HR Heart rate
MAP Mean arterial pressure = (SBP-DBP)/3 + DBP

Ethical considerations

No identifying information was collected and data were exported anonymously. Files were stored on the principal investigator's password protected computer at the University of Cape Town (UCT) Division of Emergency Medicine offices. Study data and information was backed up on a cloud server after weekly, with only study personnel having access.

Risk to patients

Routine vital signs done during triage will be extracted retrospectively from HECTIS. Data required from HECTIS will primarily be vital signs and disposition. There will be no extrication of other clinical information and therefore no risk to patient confidentiality or care. There will be no identification of individual patients and data will be aggregated thereby ensuring minimal or no risk to patients. A waiver of written consent will be applied for the study since data needed will not pose any risks of breaching patients' rights or compromise care.

Risk to the community

This project will not constitute any risk for the community of Mitchells Plain. This research project will utilise data already captured electronically and will have the potential to benefit the community via improved use of available resources for improved patient outcomes.

Risk to the institution

There will be no potential or apparent risk to Mitchells Plain Hospital which is the institution where this study will be taking place. Institutional approval will be obtained from both Mitchells Plain Hospital and ethical approval will also be sought from the HREC of the University of Cape Town.

This study received ethical approval from the University of Cape Town Human Research Ethics Committee HREC: 236/2020.

Results

During the study period of 24 months, a total of 61 329 patients ≥ 18 years old presented to the EC. Of the eligible cohort, 730 (1.2%) were excluded: 57 (7.8%) were dead on arrival, 510 (1.7%) absconded and 163 (22.3%) refused hospital treatment and left before completion of care. The final sample included 60 599 participants. All triage data were complete.

Clinical characteristics and outcomes

Critical outcomes were present in 29 594 (49%) of the sample with 26033 (88%) being admitted, 510 (1,7%) died while under the care of the EC and 3 051 (10.3%) being transferred to ICU, HCU or other department in a tertiary hospital (Table 2). Although there was a female preponderance (51%), a bigger proportion of males had critical outcomes (51% vs 47%, $p<0.05$). Critical outcomes were more prevalent in the older population (≥56 years old). A total of 17% of presentations were trauma related but presentations with no trauma had a higher prevalence of critical outcomes (50% vs 44%, $p<0.05$). The TEWS categories were dominated by the Green (53%) and Yellow groups (30%), in contrast to the Yellow (42%) and Orange (51%) groups in the SATS categories. A higher prevalence of critical outcomes occurred in the Red and Orange TEWS categories, as opposed to the SATS Red and Orange categories (Orange: 72% vs 57% and Red: 90% vs 87%). The median age was statistically higher in those who had critical outcomes, even though not clinically relevant (40 vs 39 years, $p<0.001$) (Table 3). All vital signs and calculated markers were significantly different between the two groups ($p<0.001$). The largest difference occurred with the Heart rate ,(95 bpm vs 88 bpm, $p<0.001$). systolic BP (126 mm Hg vs 130mm Hg, $p<0.001$) and Age shock index (29.54 vs 25.56, $p<0.001$).

Table 2: Descriptive statistics for demographics, triage information and dispositions (Row%)

n (row%)	Total n=60 599	Critical outcome n=29 594 (49%)	No critical outcome n=31 005 (51%)
Age (years)			
18-25	9 753	4 514 (46%)	5 239 (54%)*
26-35	15 841	7 722 (49%)	8 119 (51%)
36-45	11 007	5 318 (48%)	5 689 (52%)
46-55	8 243	3 871 (47%)	4 372 (53%)*
56-65	7 923	3 943 (50%)	3 980 (50%)
66-75	5 304	2 837 (54%)*	2 467 (47%)
>75	2 528	1 389 (55%)*	1 139 (45%)
Gender			
Male	29 600	14 972 (51%)*	14 628 (49%)
Female	30 999	14 622 (47%)	16 377 (53%)*
TEWS Category			
Green	32 335	11 746 (36%)	20 589 (64%)*
Yellow	18 062	10 048 (56%)*	8 014 (44%)
Orange	7 592	5 449 (72%)*	2 143 (28%)
Red	2 610	2 351 (90%)*	259 (10%)
SATS Category			
Green	1 072	280 (26%)	792 (74%)*
Yellow	25 276	8 811 (35%)	16 465 (65%)*
Orange	31 073	17 738 (57%)*	13 335 (43%)
Red	3 178	2 765 (87%)*	413 (13%)
Trauma			
Yes	10 016	4 391 (44%)	5 625 (56%)*
No	50 583	25 203 (50%)*	25 380 (50%)
Admitted	26 033		
Deceased	510		
Transferred out	3 051		
ICU	123		
HCU/Tertiary	1397		
Other	1 531		

TEWS Triage early warning score. SATS South African Triage Scale. ICU Intensive care unit. HCU High care unit. Percentages may not add to 100% due to rounding.
* Significantly higher proportion ($p<0.05$)

Table 3: Descriptive statistics for age, vital signs and clinical markers, Median (IQR)

Median (IQR)	Total	Critical outcome	No critical outcome
Age (years)	39 (29-56)	40 (29-57)*	39 (28-55)
RR (breaths/minute)	18 (16-20)	18 (16-20)*	18 (16-20)
HR (beats/minute)	91 (78-105)	95 (80-110)*	88 (76-101)
SBP (mm Hg)	128 (114-144)	126 (111-143)	130 (117-146)*
DBP (mm Hg)	79 (69-90)	78 (67-89)	80 (71-90)*
Temperature (C)	36.5 (36.1-36.9)	36.5 (36.1-36.9)*	36.5 (36.2-36.8)
TEWS score	2 (1-4)	3 (2-5)*	2 (1-3)
MAP (mm Hg)	95.67 (85.00-107.33)	94.00 (82.67-106.33)	97.33 (87.00-108.00)*
Shock index (SI)	0.70 (0.57-0.85)	0.74 (0.60-0.92)*	0.67 (0.55-0.80)
Modified shock index (MSI)	0.94 (0.78-1.14)	1.00 (0.82-1.23)*	0.90 (0.76-1.07)
Age shock index (ASI)	27.30 (19.96-38.24)	29.54 (21.13-41.87)*	25.60 (19.14-34.94)

RR Respiratory rate. HR Heart rate. SBP Systolic blood pressure. DBP Diastolic blood pressure.
TEWS Triage early warning score. MAP Mean arterial pressure. IQR interquartile range (25^{th}-75^{th})
All variables were significantly different at p<0.001 (Mann-Whitney U-test)
* Significantly higher median

Predictive values for markers for critical outcomes

Table 4 depicts the predictive value of selected clinical markers to predict critical outcomes. Even though the specificity of the markers is mostly high (>95%), only two of the markers had positive likelihood ratios that increased the probability of critical outcomes significantly (≥5). A red SATS triage category (+LR = 7.2) and SI ≥1.3 (+LR = 4.9) were the only two predictors of critical outcomes in the total population with any significant clinical value. The same two markers performed reasonably well for both patients with trauma and without trauma. A total of 87% of all patients with a Red SATS category had a critical outcome. An Orange triage category had very low positive predictive values (<60%) in all three categories and positive likelihood ratios (<2) to predict critical outcomes for all three cohorts.

Predictive values of markers for individual outcomes

Table 5 assesses the predictive values of selected clinical markers for each critical outcome stratified. The SATS Red and SI>1.3 once again were the only markers with significant value (+LR = 13.3 and +LR

= 5.2 respectively) for predicting mortality. All other markers and triage categories do not change the likelihood for critical outcomes significantly. A total of 10% of all patients triaged RED died while under the care of the EC and 71% of all patients with a SI≥1.3 required admission.

A total of 3 174 (5.2%) of all patients had a Red SATS category and 1 319 (2.3%) of all patients had a SI≥1.3. Of the patients who do not have a Red SATS category, 1.4% had a SI≥1.3.

Table 4: Accuracy of metrics to predict critical outcomes

	Sensitivity	Specificity	PPV	NPV	LR+	LR-
Total sample						
SATS Red	9.3%	98.7%	87.0%	53.3%	7.2	0.9
SATS Orange	59.9%	57.0%	57.1%	59.8%	1.4	0.7
SI ≥0.7	57.4%	57.1%	56.1%	58.4%	1.3	0.7
SI ≥1	17.4%	93.3%	71.2%	54.2%	2.6	0.9
SI ≥1.3	3.9%	99.2%	82.7%	52.0%	4.9	1.0
ASI ≥50	14.8%	92.5%	65.4%	53.2%	2.0	0.9
MSI ≥0.9	63.4%	50.1%	54.8%	58.9%	1.3	0.7
MSI ≥1.3	19.6%	92.0%	69.9%	54.5%	2.5	0.9
Trauma						
SATS Red	13.1%	98.6%	88.3%	59.3%	9.4	0.9
SATS Orange	61.3%	59.3%	54.1%	66.3%	1.5	0.7
SI ≥0.7	52.9%	55.7%	48.3%	60.3%	1.2	0.8
SI ≥1	11.4%	94.8%	63.2%	57.8%	2.2	0.9
SI ≥1.3	2.6%	99.4%	76.9%	56.7%	4.3	1.0
ASI ≥50	4.6%	98.2%	66.9%	56.9%	2.6	1.0
MSI ≥0.9	59.2%	49.0%	47.6%	60.6%	1.2	0.8
MSI ≥1.3	14.2%	93.2%	62.2%	58.2%	2.1	0.9
No trauma						
SATS Red	8.7%	98.7%	86.7%	52.1%	6.7	0.9
SATS Orange	59.7%	56.5%	57.7%	58.5%	1.4	0.7
SI ≥0.7	58.2%	57.4%	57.6%	58.0%	1.4	0.7
SI ≥1	18.4%	93.0%	72.2%	53.4%	2.6	0.9
SI ≥1.3	4.1%	99.2%	83.4%	51.0%	5.1	1.0
ASI ≥50	16.6%	91.2%	65.3%	52.4%	1.9	0.9
MSI ≥0.9	64.1%	50.3%	56.2%	58.5%	1.3	0.7
MSI ≥1.3	20.5%	91.7%	71.0%	53.7%	2.4	0.9

PPV Positive predictive value. NPV Negative predictive value. LR+ Positive likelihood ratio. LR- Negative likelihood ratio. SATS South African Triage Scale. SI Shock index. ASI Age shock index. MSI Modified shock index

Table 5: Accuracy of metrics to predict critical outcomes for each patient outcome

	Sensitivity	Specificity	PPV	NPV	LR+	LR-
Deceased						
SATS Red	62.4%	95.2%	10%	99.7%	13.0	0.4
SATS Orange	32.4%	48.6%	0.5%	98.8%	0.6	1.4
SI ≥0.7	51.0%	50.0%	0.9%	99.2%	1.0	1.0
SI ≥1	26.7%	88.2%	1.9%	99.3%	2.3	0.8
SI ≥1.3	11.4%	97.8%	4.2%	99.2%	5.2	0.9
ASI ≥50	30.2%	89.1%	2.3%	99.3%	2.8	0.8
MSI ≥0.9	53.5%	43.5%	0.8%	99.1%	0.9	1.1
MSI ≥1.3	28.6%	86.4%	1.7%	99.3%	2.1	0.8
Admission						
SATS Red	7.2%	96.2%	59.1%	57.9%	1.9	1.0
SATS Orange	60.0%	55.3%	40.3%	64.8%	1.3	0.7
SI ≥0.7	58.4%	56.3%	50.2%	64.3%	1.3	0.7
SI ≥1	17.7%	92.4%	63.8%	59.9%	2.3	0.9
SI ≥1.3	3.8%	98.8%	71.4%	57.7%	3.2	1.0
ASI ≥50	15.2%	92.0%	58.8%	59.0%	1.9	0.9
MSI ≥0.9	64.5%	49.5%	49.0%	64.9%	1.3	0.7
MSI ≥1.3	19.8%	91.0%	62.3%	60.1%	2.2	0.9
Transferred out						
SATS Red	18.7%	95.5%	17.9%	95.7%	4.2	0.9
SATS Orange	63.7%	49.4%	6.3%	96.2%	1.3	0.7
SI ≥0.7	50.1%	50.0%	5.1%	95.0%	1.0	1.0
SI ≥1	13.1%	88.2%	5.5%	95.0%	1.1	1.0
SI ≥1.3	3.3%	97.8%	7.2%	95.0%	1.5	1.0
ASI ≥50	9.3%	88.8%	4.2%	94.9%	0.8	1.0
MSI ≥0.9	55.5%	43.4%	4.9%	94.8%	1.0	1.0
MSI ≥1.3	15.9%	86.4%	5.9%	95.1%	1.2	1.0

PPV Positive predictive value. NPV Negative predictive value. LR+ Positive likelihood ratio. LR- Negative likelihood ratio. SATS South African Triage Scale. SI Shock index. ASI Age shock index. MSI Modified shock index

An area under the curve (AUROC) analysis (Supplementary table 1) depicts very low discrimination across all indices for all outcomes.

Discussion

This study aimed to assess the value of SI, MSI and ASI to predict critical outcomes in all adult patients presenting to a district level emergency centre in South Africa and demonstrated that patients with a SI≥1.3 have a significantly higher likelihood of having a critical outcome. This remains consistent whether or not patients present with trauma, and is specifically true for patients who die while under the care of the EC. Even though a red SATS triage category far outperformed all selected markers for all patient cohorts, an orange SATS category added little to no value in predicting critical outcomes. Whether incorporating SI in the triage process adds any tangible clinical value remains to be assessed

but it is postulated that it may improve and expedite the identification of patients with potential critical outcomes, especially if not triaged red.

Mitchells Plain Hospital EC and many other busy ECs are often overwhelmed with patients awaiting a consultation when acute surge measures have failed to meet the capacity-demand mismatch. The typical scenario usually involves several patients triaged predominantly Yellow and Orange. As evident from the results from this study, a triage category of Orange (and presumably Yellow) has little to no value in predicting critical outcomes. When faced with numerous patients with an Orange or Yellow triage category, clinicians either decide to consult them chronologically (first come first serve) or using their gestalt to 'sub-triage' patients within a triage category. Neither however, have any evidence that it improves patient outcomes. Knowing the probability of a critical outcome at triage would assist this process.

The SATS tool was developed, amongst other, to expedite the delivery of time-critical treatment for patients with life-threatening conditions. It also aids in streaming of less urgent patients. Even though its primary function is not to identify the cohort of patients that may have a critical outcome, a Red SATS category did increase the likelihood significantly (+LR = 7.2). It is however not nearly as sensitive enough on its own as only 5.2% of all patients triaged red and nearly one in two of all adults in this sample had critical outcomes. A SI≥1.3 as clinical marker and threshold will add another 2.3% to this cohort, and is especially valuable in patients who are not triaged as red. This may enable a more judicious and timely decision-making process and apportioning of resources by identifying which patients have a high likelihood of having a critical outcome. The poor discrimination from the AUROC analysis is expected, considering that the characteristics that are most useful to rule-in critical outcomes are specificity and positive likelihood ratio and not necessarily the relationship between sensitivity and specificity.

Incorporating calculated clinical markers like SI into existing triage tools may not be feasible if the application of complex calculations would create delays and complicate the process. Electronic patient management tools that incorporate the triage process is however prevalent and, on the rise, even in LMICs and therefore feasible in numerous settings. (26,27) These electronic systems would then be programmed to calculate the markers routinely and alert clinical staff if certain thresholds are reached. As example, triage alerts have been incorporated into the HopScore, (28) an electronic outcomes-based emergency triage system developed at John Hopkins university to support objective triage decisions and to improve patient differentiation based on outcomes data. When compared to the ESI, it has been found to have improved risk stratification by identifying low risk patients, allowing healthcare workers to focus their time and attention on patents with a higher acuity. The time to

disposition decision decreased by 58 minutes and overall waiting time by 10 minutes, however time from arrival to discharge was unchanged. McColl et al(29) found that triage alerts of potentially septic patients together with other components of a new sepsis management bundle resulted in an expedited and more aggressive approach to sepsis management. This caused a dramatic increase in septic protocol use and substantial decrease in mortality among septic patients. Johnson et al (30) also introduced a brief alcohol and substance abuse screening into the triage process of an urban Hospital EC. This improved high screening rates. Patients who had positive answers to the screening questions were flagged at triage electronically to alert the health education specialists that the patient required intervention and referral to treatment (SBIRT) programme. They were also automatically entered into a SBIRT patient list.

Utilising clinical markers as triage alerts to predict critical outcomes like mortality, hospital admission and transfers to HCU, and ICU confers great advantage straight from the initial patient-hospital contact. This advantage can even be extrapolated to the prehospital phase of emergency care where health care providers can be enabled to make critical decisions regarding which facility or level of care patients need to be transported to, based on predicted resources required. Relaying this information to the receiving facility also helps with planning and preparation for the patient's arrival. Activating the trauma team, cardiac catheterization laboratory and relevant specialties needed for a critically ill patient can then be done before arrival, potentially improving time to definitive care.

Even though this is one of the largest studies to date in LMICs that utilised electronic triage data to assess the predictive value of clinical markers at triage on critical outcomes, there are a few limitations. Triage accuracy depends on accurate data input and could have potentially affected the outcomes of this study. Triage accuracy at Mitchells Plain Hospital is however being monitored as part of a continuous quality improvement project and very few errors are expected. Admission practices are assumed to be generalisable at least within district hospitals and regional hospitals within the Western Cape as practices and treatment guidelines and referral pathways are standardised. The information herein is therefore expected to be externally valid for district and regional hospital using SATS.

Future studies should expand this assessment to the paediatric and adolesce population as they were not included. More complex machine learning and systems utilising artificial intelligence should be utilised to identify alerts and triggers at triage to warn clinicians about potential critical outcomes. Future studies should investigate the ideal thresholds for these markers to enable uniformity and there should be further studies to validate the results of this study in different socio-economic and

patient populations and investigate whether triage alerts actually impact patient care and improve patient throughput.

Conclusion

The study demonstrated that patients with a SI≥1.3 have a significantly higher likelihood of having a critical outcome, whether the presenting complaint is trauma related or not, especially to predict mortality while under the care of the EC. Incorporating this threshold into the triage process to generate patient alerts for clinicians, could result in a change in behaviour – to prioritise the consultation and/or to intensify the treatment plan. Triage tools like the SATS was developed to expedite the delivery of time-critical treatment for patients with life-threatening conditions and to aid the streaming of less urgent patients. Their primary function is not to identify the cohort of patients that may have a critical outcome, even though there is a need for this. This is particularly necessary in settings where there is a significant capacity-demand mismatch and where surge interventions have failed to meet the demand. With electronic triage tools becoming more prevalent, even in LMICs, incorporating triage alerts is both possible and feasible. Whether incorporating SI in the triage process adds any tangible clinical value remains to be assessed but it is postulated that it may improve and expedite the identification of patients with potential critical outcomes, especially if not triaged red, and may improve patient throughput.

Funding

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Dissemination of Results

The findings of this study have been disseminated to the relevant Emergency Centre and Hospital managers, as well as to the Faculty of Emergency Medicine Cape Town.

Authors' Contributions

Authors contributed as follow to the conception or design of the work (CH, CvK and PA); the acquisition (CH), analysis (CH), or interpretation (CH, PA) of data for the work; and drafting the work (CH and PA) or revising it critically for important intellectual content (CH, CvK, and PA): PA contributed 55%; CH

40%; and CvK 5%. All authors approved the manuscript to be published and agreed to be accountable for all aspects of the work.

Declaration of Competing Interests

CH is an associate editor of the African Journal of Emergency Medicine. CH was not involved in the editorial workflow for this manuscript. The African Journal of Emergency Medicine applies a double blinded process for all manuscript peer reviews. The authors declared no further conflicts of interest.

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Disclaimer

We declare that the views expressed in this submission are our own and do not reflect the official position of the University of Cape Town.

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Supplementary tables and figures

Supplementary table 1: Area under the curve (AUROC) values for each predictor and selected outcomes

	Area	Std. Error	P	95% CI
Critical outcomes				
Total sample				
SI	0.602	0.002	<0.001	0.597-0.606
MAP	0.446	0.002	<0.001	0.441-0.451
MSI	0.603	0.002	<0.001	0.599-0.608
ASI	0.582	0.002	<0.001	0.578-0.587
Trauma				
SI	0.562	0.006	<0.001	0.551-0.573
MAP	0.438	0.006	<0.001	0.427-0.449
MSI	0.566	0.006	<0.001	0.555-0.578
ASI	0.529	0.006	<0.001	0.518-0.541
No trauma				
SI	0.609	0.002	<0.001	0.604-0.614
MAP	0.447	0.003	<0.001	0.442-0.452
MSI	0.609	0.002	<0.001	0.605-0.614
ASI	0.587	0.003	<0.001	0.582-0.592
Mortality				
Total sample				
SI	0.582	0.017	<0.001	0.548-0.616
MAP	0.390	0.018	<0.001	0.355-0.425
MSI	0.584	0.017	<0.001	0.549-0.618
ASI	0.683	0.015	<0.001	0.653-0.713
Trauma				
SI	0.566	0.048	0.068	0.472-0.661
MAP	0.453	0.050	0.200	0.355-0.552
MSI	0.563	0.048	0.084	0.486-0.658
ASI	0.552	0.046	0.155	0.462-0.641
No trauma				
SI	0.585	0.018	<0.001	0.548-0.621
MAP	0.379	0.019	<0.001	0.342-0.416
MSI	0.587	0.019	<0.001	0.550-0.623
ASI	0.706	0.016	<0.001	0.675-0.736

SI Shock index MAP Mean arterial pressure MSI Modified shock index ASI Age shock index CI Confidence interval

PART B: Addenda

Addendum 1: Author guideline: African Journal of Emergency Medicine

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Dissertation Proposal

The value of shock index, modified shock index and age shock index in predicting critical outcomes in a district level emergency centre

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Lead investigator:
Dr Patrick Aleka
University of Cape Town
ALKPAT001
patrickaleka@yahoo.com

Supervisors:
Dr Clint Hendrikse
Division of Emergency Medicine
Department of Surgery
University of Cape Town
clint.hendrikse@uct.ac.za

Dr Candice Van Koningsbruggen
Division of Emergency Medicine
Department of Surgery
University of Cape Town
candice.vankoningsbruggen@uct.ac.za

Declaration

I, Dr Patrick Aleka, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Patrick Aleka

22 April 2022

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Acronyms and abbreviations

AMI	Acute Myocardial Infarction
ASI	Age shock index
AUROC	Area under receiver operating characteristic
EC	Emergency Centre
ED	Emergency Department
HECTIS	Hospital and Emergency Centre Tracking Information System
HR	Heart rate
HREC	Human Research Ethics Committee
ICU	Intensive Care Unit
LMIC	Low- and middle-income countries
MAP	Mean Arterial Pressure
MIC	Middle-income countries
MSI	Modified shock index
RHT	Refusal of hospital treatment
SATG	South African triage Group
SATS	South African triage scale
SBP	Systolic Blood Pressure
SI	Shock Index
STEMI	ST elevation Myocardial Infarction
UCT	University of Cape Town

Abstract

Introduction

Emergency patients often present with complex pathology and may appear well at triage. Flagging very ill patients from triage to prompt quick intervention and proper allocation of needed resources to such patients is important and can impact on patient outcomes. The Shock Index (SI), Modified Shock Index (MSI) and the Age Shock Index (ASI) are indices that have been assessed as useful early warning tools from triage vital signs to identify such patients. This study aims to assess the diagnostic accuracy of Shock Index, Age Shock Index and Modified Shock Index on critical outcomes of all adult patients presenting to a district level emergency centre.

Methodology

This diagnostic study will be performed as a retrospective observational study, using data from the Hospital and Emergency Centre Tracking Information System (HECTIS) database at Mitchells Plain Hospital, a district level emergency centre, located in Cape Town, South Africa. All adult patients (age greater or equal to 18 years of age) who presented to Mitchells Plain Hospital EC between 1st January 2018 and 31st December 2019 (24 months) will be eligible for inclusion. Sensitivity, specificity and likelihood ratios will be calculated for shock index, modified shock index and age shock index as predictors of critical outcomes of EC patients. 95% Confidence intervals will be presented and $p<0.5$ will be accepted as statistical significance.

Ethical considerations

Routine vital signs done during triage will be extracted retrospectively from an existing database, HECTIS. No personal details will be included in the dataset and data will be anonymised from the outset. A waiver of consent will be applied for the study since data needed will not pose any risks of breaching patients' rights or compromise care. Ethical approval will be sought from University of Cape Town HREC and institutional approval thereafter from the National Health Research Database (NHRD).

Conclusion

There is a need for more cost-effective ways to utilise resources especially in LMIC, hence the effort by various studies to identify tools which can help in early identification of very sick patients. Traditionally the SATS and it's TEWS have been used in South Africa. However, newer indices like the MSI and ASI are now being studied because they confer distinct advantages over the vital signs only. These are all easily obtainable, non-invasive early variables we can obtain at triage to help in improving

outcomes without extra strain on available resources. This study will hopefully shed some light on the value of these indices to predict critical outcomes of all patients presenting to Emergency Centres.

Introduction

Background

Triage is the first step in an emergency centre (EC) consultation and provides valuable information on the current condition of the patient and urgency of required medical intervention – sorting patient in order of priority. The South African Triage system(SATS) is widely used in both South Africa, as well as in other low- and middle-income countries(1). Emergency patients often present with complex pathology and may appear well at triage. Flagging very ill patients from triage to prompt quick intervention and proper allocation of needed resources to such patients is important and can impact on patient outcomes. The Shock Index (SI), Modified Shock Index (MSI) and the Age Shock Index (ASI) are indices that have been put forward as useful early warning tools from triage vital signs to identify such patients.(2)(3).

The Shock index is defined as the heart rate (HR) divided by the systolic blood pressure (SBP), and is the most studied of the SI, MSI and ASI. It is widely considered a good predictor of mortality in most acute conditions encountered in the emergency room: it has been shown to be an indicator of infarct size in STEMI(4); is better than conventional vital signs in identifying acute, critical illness in the Emergency Department (ED)(5); is a predictor of hospital admission and inpatient mortality in EC patients(6) and has been shown to be a predictor of massive transfusion in blunt trauma patients in the pre hospital setting(7).

The MSI is an important predictor of mortality in patients presenting to the EC and it may be better than blood pressure and heart rate(8) It is calculated as the heart rate divided by the mean arterial pressure (MAP), thus incorporating the diastolic pressure. The MAP is a good indicator of tissue perfusion status, and the diastolic pressure of a shocked patient will decrease earlier than the systolic, so the MSI is seen to be more clinically helpful within 24 hours of ICU admission(9). A study from the United States of America found that it is also a good predictor of mortality in emergency patients(8). Many other studies have shown the value of the MSI as a predictor of seven-day outcome in STEMI, and that it can be used to identify high risk STEMI patients(7). MSI has also been used to predict mortality in early sepsis(10) and even in the prehospital trauma setting(11).

The Age Shock Index, like the MSI, is another derivative of the SI. It is defined as age multiplied by the SI. As emergency centre patients vary in age, and as there are numerous physiological and anatomical differences at the two extremes of age, there is an obvious need for another derivative of the shock index that takes the factor of age into consideration. Studies have shown that the ASI is superior to the SI and MSI for predicting long term prognosis in Acute Myocardial Infarction (AMI)(12). One study

showed it to be more predictive of in hospital mortality in geriatric trauma patients than the SI or MS(13). Paediatric adjusted shock index has also been shown to facilitate identification of injured children with poorer outcomes in resource strained settings(14). It is less extensively studied in the emergency setting than the SI.

The SATS was developed by the South African Triage Group (SATG) and is a widely used tool in South Africa and a few other low- and middle-income countries (LMIC). The SATS is a physiology and symptom-based scale which prioritises patients into one of four colours and can be used in hospital Emergency Centres as well as in the prehospital setting. Some studies have validated it for use in South Africa(1), and this use cuts across public, private and prehospital settings.

The SATS consists of 3 parts: the clinical discriminator list (part 1), the Triage Early Warning Score (TEWS) (part 2) and the additional investigations (part 3). The clinical discriminator list is used together with the TEWS and the additional investigations. The provider calculates the TEWS and checks additional investigations once emergency clinical discriminators have been cleared. The patient is then given a colour code according to priority.

Different vital signs-based triage systems exist world-wide and they are all relevant for the settings in which they are applied. The ability to identify and flag very sick patients especially in usually crowded, busy emergency departments with the available and sometimes scarce resources is important. It has brought indices or markers such as the Si, MSI, and ASI into greater significance hence the need for more studies.

Motivation

There is a need for more cost-effective ways to utilise resources especially in LMIC, hence the effort by various studies to identify tools which can help in early identification of very sick patients. Traditionally the SATS and its TEWS have been used in South Africa. However, newer indices like the MSI and ASI are now being studied because they confer distinct advantages over the vital signs only. These are all easily obtainable, non-invasive early variables we can obtain at triage to help in improving outcomes without extra strain on available resources.

Emergency centres are most often the patients' entry point into the health care system. They are usually busy and crowded with a high turnover of patients. Access block is also a challenge due to a number of factors unique to the emergency centres. A supply and demand mismatch between resources and the need for services arises to add to the other challenges already prevalent in the emergency health care setting. Hence the obvious need to be able to flag patients who need prompt intervention from the onset to improve outcomes.

There is a paucity of studies in Africa assessing these indices: a study in South Africa showed that Shock indices were poor at triaging trauma patients (2); another compared traditional vital signs against shock index and age-based markers in trauma(15), one study on geriatric patients done in Nigeria showed the SI along with other vital signs were predictors of increased mortality in older patients(16).

This study will investigate the diagnostic value of the above-mentioned indices and the and SATS in the emergency centre to predict critical outcomes in a resource constrained environment in South Africa and hopefully contribute to the information already available globally on this topic. The results will contribute to the data pool needed to assess the potential for the SI, MSI, ASI or SATS to be used as frontline tools in emergency rooms in South Africa for improved patient outcomes, through shorter hospital stays and lower hospital mortality.

Research question

In all adult patients presenting to a district level emergency centre, what is the diagnostic accuracy of shock index, modified shock index and age shock index to predict critical outcomes?

Aim

To assess the value of shock index, modified shock index and age shock index in predicting critical outcomes in a district level emergency centre.

Objectives

1. To assess the SI, MSI and ASI on all adult patients presenting to the EC over the study period.
2. To assess sensitivity, specificity, positive likelihood ratio and Area under receiver operator characteristic curve (AUROC) FOR SI, MSI, and ASI for critical outcomes of all adult patients presenting to the EC in the study period.

Critical outcomes will be defined by the investigators as having any of the following:

1) EC death (died while under EC care – unreferred patients)

2) patients referred to a high care unit (HCU)

3) patients referred to an intensive care unit (ICU)

4) patients who required care in the resuscitation area

5) patient who were transferred to theatre from the EC

Methodology

Study design

This diagnostic study will be performed as a retrospective observational study, using data from the Hospital and Emergency Centre Tracking Information System (HECTIS) database at a district level hospital emergency centre.

Study setting

This study will be performed at Mitchells Plain Hospital EC, which is a District level hospital EC located in Cape Town, South Africa. It is one of the hospitals in the Mitchells Plain Health District of the Metro region and is located approximately 33km from the Cape Town city centre. The Hospital serves the population of Mitchells Plain and the greater part of a nearby township called Philippi, a total of approximately 550,000 people. The demographics of Mitchells Plain include low- to middle-income families, about 90% of whom are coloured. It also serves the neighbouring township of Philippi, which consists out of predominantly low- income black families. The EC attends to an average of 4500 adult patients per month. 5% of the total are triaged 'Red', 47% triaged 'Orange', 43% triaged 'Yellow' and a further 3% triaged 'Green'. The EC also has an overall admission rate of 37%.

Study population and sampling

Inclusion criteria

All adult patients (age greater or equal to 18 years of age) who presented to Mitchells Plain Hospital EC between 1st January 2018 and 31st December 2019 (24 months) will be eligible for inclusion.
A study period of 24 months was chosen to limit the effects of month-to month and seasonal variance.

Exclusion criteria

All patients with incomplete triage data were excluded

Data collection and management

Patients to be included in the study will be identified from HECTIS, which is the electronic patient register in use in the hospital already. Triage data for each participant meeting the inclusion criteria will be extracted onto a spreadsheet. Their SATS, SI, MSI and ASI will then be calculated using this data. Variables to be identified at this stage include age, gender, the triage category, all the vital signs and disposition of the patient. No identifying information will be collected, and the data set will be anonymised from the onset.

Missing data or incomplete records

Patients with incomplete triage data will be excluded from the study as these need to be clearly documented vital signs for each participant. The number of missing cases will be clearly identified, together with the demographics of the patients, if the total missing data exceeds 5%. This will allow for comparison to be made between the relevant patients and the missing information. The data will be generated from an existing data base and so only patients with complete vital signs will be extracted from the HECTIS.

Variables and data source

Source: HECTIS. This is an electronic registry of all patients that are managed in the emergency centre. It includes information regarding patient demographics, location within the EC, ICD-10 diagnostic codes, and process times. The electronic tool also integrated the South African Triage Scale (SATS).

Variables that will be collected include Age, gender, heart rate, blood pressure, triage category disposition from EC, whether or not patient was treated in the Resuscitation bay or not.

Critical outcomes will be defined as any of the following:

1) EC death (died while under EC care – unreferred patients)

2) patients referred to a high care unit (HCU)

3) patients referred to an intensive care unit (ICU)

4) patients who required care in the resuscitation area

5) patient who were transferred to theatre from the EC

Data safety and monitoring

Data will be obtained from the HECTIS database as described above and further calculations and information will be performed on the data set. No identifying information will be collected, and data will be exported anonymously. A request to the database manager will include only the variables listed above for the study period. Files will be stored centrally at the University of Cape Town (UCT) Division of Emergency Medicine offices and will be password protected. Study data and information will also be backed up on a cloud server weekly, with access only by study personnel.

Data Analysis

Data will be presented using descriptive and inferential statistics Data were analysed by the principal investigator with the help of SPSS Version xx.Continuous variables, such as age, will be presented as medians and interquartile ranges, while categorical variables will be presented as proportions and percentages as appropriate. Where appropriate, 95% confidence intervals (CI) for point estimates will be provided. Statistically significant differences between groups (categorical variables) will be calculated by using the Fisher's exact test or the X^2 test, depending on the sample characteristics. Statistical significance will be defined as p-value <0.5. Sensitivity, specificity and Likelihood ratios will be calculated for each variable as a predictor of critical outcomes. Cut-offs for each variable will be extrapolated from existing literature:(17)

1) Shock index (SI): ≥0.7; ≥1.0; ≥1.3 (3 values)

2) Age Shock index (ASI): ≥50 (single value)

3) Modified Shock Index (MSI): ≥0.9; ≥1.3 (2 values)

4) South African Triage Scale (SATS): red; orange (2 values)

Combination of SATS and various indices will also be assessed as predictor of critical outcomes.

Ethical considerations

Risk to patients

Routine vital signs done during triage will be extracted retrospectively from HECTIS. Data required from HECTIS will primarily be vital signs and disposition. There will be no extrication of other clinical information and therefore no risk to patient confidentiality or care. There will be no identification of individual patients and data will be aggregated thereby ensuring minimal or no risk to patients. A waiver of written consent will be applied for the study since data needed will not pose any risks of breaching patients' rights or compromise care.

Risk to the community

This project will not constitute any risk for the community of Mitchells Plain. This research project will utilise data already captured electronically and will have the potential to benefit the community via improved use of available resources for improved patient outcomes.

Risk to the institution

There will be no potential or apparent risk to Mitchells Plain Hospital which is the institution where this study will be taking place. Institutional approval will be obtained from both Mitchells Plain Hospital and ethical approval will also be sought from the HREC of the University of Cape Town.

Strengths and limitations

Strengths

This will be the first study of its kind investigating different indices and SATS as predictors of critical outcomes. It utilises an existing database and includes a large sample size – estimated 60 000 entries – this will allow for statistically significant inferences. If these variables do prove helpful, it will not cost any additional resources to implement in real practice; this is due to the electronic triage process that can be programmed to automatically flag patients at risk for critical outcomes. This population is generalisable to the wider population of the Western Cape and most of South Africa, so results should be externally valid.

Limitations

The triage information that is keyed into HECTIS is dependent on accurate data entry. Mitchells Plain Hospital triage accuracy is continuously being monitored as part of a continuous quality improvement project and very few inaccurate details are expected. Patients are nursed in the resuscitation room based on clinical gestalt of clinicians or discretion of senior nurses. It is not based on triage category but rather the need for continuous monitoring or an advanced procedure. Nursing ratios and training is also improved in the resuscitation room. The inclusion of the resuscitation room as critical outcomes is a pragmatic variable that is relevant to the setting. Variances as a result of its inclusion will be acceptable, considering how patents access the resuscitation room.

Data dissemination

Publication in a peer review journal is an anticipated result for this research work. The information gained from this project will be presented to Mitchells Plain Hospital Senior Clinicians, as well as the Emergency Medical Division of the University of Cape Town.

Project timeline

Table 1: Project timeline

	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec
EMDRC	X	X	X									
Ethics			X	X								
Hospital				X	X							
Permission												
Data Collection						X						
Data Analysis							X					
Write up							X	X	X			
Submission										X	X	X

Budget and resources

Budget

The total budget of R1300 will be borne by the entire research team.

Available resources

Hardware: Laptop, hard drive already available, no expenditure

Software: Word processing software, referencing software, data migration software and statistical analysis software already available. No expenditure.

Table 2: Budget

Item	Description	Unit cost	Units	Total cost
Consumables				
Material and supplies				
1.Office supplies , printing and reproduction for data collection	Stationery - pens, notepads, files			R500.00
2.Office supplies, printing and reproduction for reports	Printing - data collection, reports, paper.			R300.00
Research Travel				
1.Travel to sites	Travel to MPH x3 trips= 30km x 10 = 300km @ SARS rates			R400.00
2.Others	Travel to UCT library: 5 trips = 5km x 10 = 50km			R100.00
Total				**R1300.00**

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Addendum 3: University of Cape Town Human Research Ethics Committee Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

08 May 2020

HREC REF: 236/2020

Dr C Hendrikse
Division of Emergency Medicine
F-51 OMB
Email: clint.hendrikse@uct.ac.za
Student: - pattrickaleka@yahoo.com

Dear Dr Hendrikse

PROJECT TITLE: THE VALUE OF SHOCK INDEX, MODIFIED SHOCK INDEX AND AGE SHOCK INDEX IN PREDICTING CRITICAL OUTCOMES IN A DISTRICT LEVEL EMERGENCY CENTRE- MMED CANDIDATE DR PATRICK ALEKA

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020.

Approval is granted for one year until the 30 May 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: - Dr Morne Bezuidenhout will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Addendum 4: National Health Research Database Facility Approval

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_202005_011
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Dr Patrick Aleka, Dr Clint Hendrikse, Dr Candice Van Koningsbruggen

Re: The value of Shock Index, Modified Shock Index and Age Shock Index in predicting critical outcomes in a district level Emergency Centre

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Mitchells Plain Hospital	**Dr Jacek Marszalek**	**021 377 4782**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 22/10/2020
CC